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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,613	01/25/2002	Ralf Geiben Lynn	23659-501	2925

7590 07/29/2003

Ivor Elrifi Esq.
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
BROWN, STACY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,613	GEIBEN LYNN ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 19, 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *29-34 and 37-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,7,9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, claims 1-28 and 35-36 without traverse is acknowledged. Claims 1-48 are pending. Claims 29-34 and 37-48 are withdrawn from consideration being drawn to non-elected subject matter. Claims 1-28 and 35-36 are examined on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 5 recites improper Markush language. The last member of the group should be preceded by "and".
- Claims 6 and 14 recite "pretreating" serpin, however, it is unclear what method steps and reagents are involved in pretreating serpin. How would one of skill in the art know what step to perform by the general term "pretreating"? The claims require an additional method step indicating what is meant by "pretreating" serpin.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

a. Claims 1-5, 8-13 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lezdey *et al* (5,532,215). The claims are drawn to a method of inhibiting/decreasing HIV infectivity by contacting an HIV virion with a serpin, and incubating the two for a period of time allowing inhibition of infection. The serpin inhibits serine protease and binds heparin. The source of the serpin can be human or bovine.

Ledzey teaches a method for inhibiting HIV proliferation by inhibiting viral replication or killing the viruses on contact via human serine protease inhibitors such as alpha-1-antitrypsin (AAT) and antithrombin (abstract, col. 5, lines 17-25, and col. 6, line 31).

b. Claims 1-18, 35 and 36 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shapiro (WO 00/52034). The claims are drawn to a method of inhibiting/decreasing HIV infectivity by contacting an HIV virion with a serpin, and incubating the two for a period of time allowing inhibition

of infection. The serpin inhibits serine protease and binds heparin. The source of the serpin can be human or bovine. The serpin compound is pre-treated with elastase.

Shapiro teaches methods of inhibiting viral infection (HIV) by administering compounds having serine protease inhibitory or serpin activity (abstract). Shapiro teaches that alpha-1-antitrypsin (AAT) and thrombin have serpin activity (page 2, line 28). The serpin source is mammalian (Example 1) and dosages contain between 5-2000 mg (page 18, lines 7-12). The serpin is applied to delivery systems such as polymer matrices. One would have been motivated to pre-treat the serpin compound with elastase to maintain a balance of serine proteases and elastases (inhibitors of proteases), as taught by Shapiro(page 3, lines 14-15).

4. Claims 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey *et al* (5,532,215) or Shapiro (WO 00/52034) as applied to claims 1-18 and 35-36 above (respectively), and further in view of Hopkins (WO96/10639). The claims are drawn to a method of inhibiting HIV infection with a serpin, wherein the serpin is expressed by a producer cell comprising the serpin DNA. Lezdey and Shapiro fail to teach the expression of serpin in a producer cell.

Hopkins teaches modified serine protease inhibitors, including AAT and antithrombin (abstract). Hopkins introduces the modified AAT DNA/vector into a host cell and expresses the serpin (pages 17-18). It would have been obvious to express a serpin for use Hopkins' method to treat HIV infection. Gene expression in producer cells and gene therapy (localized expression) are well known procedures for delivery of therapeutic agents. One would have been motivated

to use Hopkins gene expression method in Lezdey's or Shapiro's method because DNA expression of therapeutic agents was a common method of delivery at the time of the invention, as evidenced by Hopkins. One would have had a reasonable expectation of success that Hopkins' method of gene delivery and expression would work in the method of Lezdey or Shapiro because they are expressing the similar proteins: AAT and modified AAT. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

5. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC

Stacy B. Chen
July 25, 2003

James C. Housel 7/27/03

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600